Review of the NICEATM/ICCVAM Five-Year Plan

by the
SACATM Five-Year Plan Working Group
(FYPWG)

Members of the FYPWG

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FYPWG Charter

- To review the Five-Year Plan (FYP) put forth by NICEATM/ICCVAM
- To ensure the FYP meets these objectives:
  1) Research, develop, translate, and validate new/revised alternative toxicity assays for integration into federal agency testing programs
  2) Identify high priority areas for new/revised alternative toxicity assays which will meet the goals of:
     - replacement
     - reduction
     - refinement

Review of the Five-Year Plan: Comments

Main Issues with FYP

- Is the draft FYP comprehensive?
- Is the draft FYP strategic?
- Is the draft FYP detailed with clearly defined priorities and milestones?
- Does the draft FYP describe clearly defined roles?
- Does the draft FYP clearly identify the gaps?
- Does the draft FYP address communicating with and engaging stakeholders?

Comprehensive?

- Impressive compilation of ongoing research and development activities and methods standardization
- Information on method-development activities
- Information on newer technologies - high throughput screening and high-content screening methods
- NICEATM/ICCVAM plan has a critical role for actualizing these methods within federal programs
- Now more than ever, a real need for a comprehensive FYP

Strategic?

- Draft plan falls short
- Recommendations:
  - Identify 2-3 high priority areas and provide a detailed plan
  - Opportunity to define and address both technical and procedural challenges
- Where will NICEATM/ICCVAM be in 5 years?

Priorities and Milestones?

- Need to clarify 2-3 highest priorities and provide timelines and milestones
- Recommendations:
  - Provide a “roadmap”
  - Consider a SWOT-type analysis
  - Map priorities and milestones onto a pipeline of research, development, translation, validation, and regulatory acceptance

Clearly Defined Roles?

- Difficult to identify roles and responsibilities of ICCVAM, NICEATM, and individual agencies
- Recommendation: provide a table

Activity	R&D Lead Agency	R&D Timeline	Translation Lead Agency	Translation Timeline	Validation Lead Agency	Validation TImeline
Method						

Gaps or Barriers Are Not Identified

- What are the gaps and barriers along the method-development, validation, and adoption pathway?
- Plan appears to be heavily weighted toward R&D, but are there gaps in planning for validation activities?
- Recommendation: Include a table of past methods reviewed and approved by ICCVAM and the agencies' actions on those tests
  - Use to identify any gaps or a barriers for current or future methods

Communicating with and Engaging Stakeholders

- FYPWG recognizes the extensive outreach efforts by NICEATM/ICCVAM to get comment and input on the Five-Year Plan
- Recommendation: FYP needs to include elements to reach out and engage stakeholders on an ongoing basis

FYPWG believes it is incumbent upon the ICCVAM agencies themselves – as critical stakeholders – to fully embrace the 3Rs and exert the leadership needed to assure that the validated methods delivered by the efforts of NICEATM and ICCVAM are actualized into regulatory testing frameworks as soon as practicable.

Discussion Questions for SACATM

(Lead Discussants Drs. “Marsman, Charles ,Dong, Bradlaw)

1. **Do you have any comments on the Working Group’s report?**
2. **Do you have any comments on the draft NICEATM-ICCVAM Five-Year Plan**
    a. **Does the draft plan adequately address the two objectives identified in the Congressional language: (1) research, development, translation, and validation of new and revised non-animal and other alternative assays for integration into federal agency testing programs and (2) identification of areas of high priority for new and revised non-animal and alternative assays for replacement, reduction, and refinement (less pain and distress) of animal tests?**

Continued

b. **Does the plan clearly articulate and address the four challenges?**

c. **Are there additional activities that NICEATM and ICCVAM should consider to facilitate the research, development, translation, and validation of new and revised alternative test methods for integration into federal regulatory testing programs that will reduce, replace, and refine (less pain and distress) animal use for regulatory testing?**

d. **Are there additional areas that NICEATM, ICCVAM, and federal agency program offices should consider as high priority for alternative test methods?**